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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

ALLERGAN PLC, ALLERGAN, INC., ALLERGAN USA, INC., ALLERGAN SALES, LLC, FOREST LABORATORIES HOLDINGS, LTD., ADAMAS PHARMA, AND ADAMAS PHARMACEUTICALS, INC.,

Defendants.

Case No.: 3:18-cv-03018-JCS

STATEMENT OF INTEREST ON BEHALF OF THE STATE OF CALIFORNIA, BY AND THROUGH THE CALIFORNIA INSURANCE COMMISSIONER

Chief Magistrate Judge Joseph C. Spero

Courtroom G
450 Golden Gate Avenue
San Francisco, CA 94102

The State of California, by and through the California Insurance Commissioner, files this Statement of Interest in support of the relator, Zachary Silbersher.

The Department of Insurance, through the Insurance Commissioner, has responsibility for enforcing the California Insurance Frauds Prevention Act, Cal. Ins. Code §§ 1871-1879.8 (the "CIFPA"), which is directed to preventing fraud on private insurers. The Department has a significant interest in stopping fraudulent practices that raise the price of prescription drugs. The Department is also concerned about the impact high drug prices have on health insurance premiums.[1] There is growing evidence that a significant driver of high drug prices is the abuse of invalid patents to exclude generic competition. Such improper "evergreening" practices raise the price of medicine to monopolistic levels for many years while patent validity is litigated.

Additionally, some provisions in the CIFPA, particularly with respect the statute's *qui tam* provisions, are similar to the federal False Claims Act. The Department therefore has an interest in ensuring that case law develops consistent with upholding the purpose underlying these statutes, because the courts will often look to federal decisions for guidance in interpreting the CIFPA. *See, e.g.*, *City of Hawthorne* ex rel. *Wohlner v. H&C Disposal Co.*, 109 Cal. App. 4th 1668, 1682, 1 Cal. Rptr. 3d 312, 321 (2003), *as modified on denial of reh'g* (July 29, 2003).

The theory of liability underlying this case—along with two other unsealed cases brought by the relator[2]—is that when brand pharmaceutical companies fraudulently obtain patents and use them to exclude generic competitors and charge monopoly prices, then all subsequent claims for payment incorporating the inflated prices are false claims. Relator's suits, if successful, may set an important precedent that would discourage drug companies from taking advantage of the *ex parte* nature of patent proceedings by withholding or misrepresenting material information relating to patentability—and thereby significantly reduce the amount governments and insurers pay for important medicines.

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[1] *See Impact on Prescription Drug Costs on Health Insurance Premiums* (California Department of Insurance: Dec. 31, 2018) (http://www.insurance.ca.gov/01-consumers/110-health/60-resources/upload/CDI-Prescription-Drug-Premium-Impact-Report-Dec-31-2018.pdf) Indeed, by some estimates nearly 25% of health care premiums are used for prescription drugs. *See* https://www.ahip.org/wp-content/uploads/2017/03/HealthCareDollar_FINAL.pdf.

[2] *See Silbersher v. Janssen Biotech, Inc.*, No. 2:19-cv-12107 (KM-HBC) (D.N.J.); and *Silbersher v. Valeant Pharms. Int'l Inc.*, No. 3:18-cv-1496-JD (N.D. Cal.).

We understand the court in *United States* ex rel. *Silbersher v. Valeant Pharm. Int'l, Inc.*, No. 3:18-cv-01496-JD (N.D. Cal. May 11, 2020), Dkt. No. 109 ("Order"), dismissed the relator's complaint on public disclosure grounds. We also understand that, relying on the Order, defendants in this case have sought to argue government authorities were placed "on notice" of the alleged fraud because of information pieced together from various patent filings with the U.S.P.T.O. We respectfully disagree with the reasoning in the Order and with the notion that government agencies are placed on notice of fraud based on patent filings.

Mr. Silbersher's suits are neither "parasitic" nor "opportunistic." We are not aware of any government agency that regularly monitors patent filings[3] to determine whether there has been a material omission or misrepresentation in applications for pharmaceutical patents, particularly given the specialized expertise and amount of resources that would be required to do so. We therefore welcome the efforts of relators like Mr. Silbersher to help identify instances where drug patents are not just invalid, but fraudulent—particularly in a case like this, where there was apparently no pre-existing government investigation concerning the alleged fraud. Such efforts, if successful, may help lower the price of medicine and the cost of health insurance, which is consistent with our mission.

Dated: June 8, 2020

Respectfully submitted,

CALIFORNIA DEPARTMENT OF INSURANCE

By: */s/ Nicholas G. Campins*

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[3] While there are differences in the definition of "public disclosure" between the federal False Claims Act and the CIFPA, we do not believe patent filings should qualify as an enumerated public forum for public disclosure purposes.